

WASTE CHARACTERIZATION OF USED SILVER NITRATE APPLICATOR STICKS

TECHNICAL INFORMATION PAPER No. 37-055-0516

PURPOSE. This document provides the rationale for characterizing used silver nitrate applicator sticks as non-infectious, ignitable and toxic hazardous waste (HW), identified by Environmental Protection Agency (EPA) hazardous waste numbers D001 and D011.

REFERENCES. See Appendix A for a list of reference information.

POINTS OF MAJOR INTEREST AND FACTS.

BACKGROUND

Silver nitrate applicators cauterize skin, stop superficial bleeding, remove warts, and remove excessive granulation and tissue around wounds. Contact with body fluids or water activates the applicator tips. Medical personnel apply the tip of each stick to the wound during treatment; once in contact with blood/fluids, the chemicals on the tip of the stick cauterize the wound and stop wound bleeding within seconds. Only the tip of the stick is actively used in treatment. One applicator with an estimated contact time of 10 to 30 seconds is sufficient for each application.

The silver nitrate applicator stick composition consists of a rigid wooden stick tipped with a solid comprised of 75% Silver Nitrate and 25% Potassium Nitrate in a form that resembles a match tip. Silver nitrate serves as a caustic antiseptic and an astringent. Potassium nitrate serves as a topical antiseptic.

HAZARDOUS WASTE CHARACTERIZATION

Oxidizer (D001 Ignitable Hazardous Waste). The silver/potassium nitrate solid is a strong irritant to skin and tissue and is an oxidizer. The EPA classifies oxidizers, defined by Title 49 Code of Federal Register (CFR) Part 173, as ignitable HW. The EPA HW number for ignitability is D001. Product safety data sheets list the product as a Department of Transportation (DOT) classified oxidizer. After treatment, visible amounts of silver/potassium nitrate solid remain on the tip of each stick because the average treatment time does not deplete all of the solid content on the tip of the stick. The solid silver/potassium nitrate remaining on each stick tip is still an oxidizer because it was not completely consumed in the treatment process.

Silver (D011 Toxic Hazardous Waste). The silver nitrate solid in the unused stick tip contains silver concentrations that exceed the 5 milligrams per liter (mg/L) toxicity characteristic leaching procedure (TCLP) limit. In September 2011, the Army Public Health Center (Provisional) (APHC (Prov)) [formerly the U.S. Army Public Health Command] conducted a waste characterization sampling study of used silver nitrate sticks to determine the silver concentrations remaining on the sticks after treatment. The APHC (Prov) Waste Management Program devised a sampling plan and procedures to collect representative samples based on clinical treatment practices of approximately 10–30 seconds of application time. Current silver nitrate stick composition and medical use remains the same as in 2011. The APHC (Prov) Laboratory analyzed seven representative samples (approximately 115 sticks per sample) for TCLP silver concentrations. All sample results exceeded the EPA HW limit of 5 mg/L by an average of 40 times the limit, indicating the sticks are HW for silver content. The EPA HW number for silver is D011.

REGULATED MEDICAL WASTE ASSESSMENT

Visible stains can occur on the stick where the treatment tip joins the wooden stick (see Appendix B). The stains are dry within minutes of treatment and are not capable of caking or sloughing off the stick. To address concerns about the stains, the APHC (Prov) conducted a regulated medical waste (RMW) assessment to determine whether the sticks require RMW management and treatment. The assessment involved a complete regulatory review, onsite treatment observations, and consultation with multiple microbiologists at U.S. Army Medical Command (MEDCOM) laboratories. As detailed in this section, the used sticks are not RMW (also referred to as infectious waste) even if visible stains exist on the sticks because —

- No free-flowing, dripping, or saturated fluids remain on used silver nitrate sticks;
- No biohazardous growth is possible on the dry sticks or dry stains; and
- No state classifies used silver nitrate sticks as infectious/regulated medical waste.

The Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard. The OSHA Bloodborne Pathogen Standard, Title 29 CFR Part 1910, Section 1910.1030(b), is the regulatory reference most states refer to when defining RMW. The MEDCOM referenced this regulation when writing MEDCOM Regulation 40-35, which applies to all continental United States Army medical treatment facilities.

An OSHA Frequently Asked Question (FAQ) response clarifies that “regulated waste” (OSHA term for infectious waste/RMW) must be free-flowing fluids or be capable of releasing fluids or caked material upon compression (see Appendix C). The OSHA

FAQ response states, "The Bloodborne Pathogens standard uses the term, "regulated waste," to refer to the following categories of waste which require special handling: (1) liquid or semi-liquid blood or other potentially infectious materials (OPIM); (2) items contaminated with blood or OPIM and which would release these substances in a liquid or semi-liquid state if compressed; (3) items that are caked with dried blood or OPIM and are capable of releasing these materials during handling; (4) contaminated sharps; and (5) pathological and microbiological wastes containing blood or OPIM."

The OSHA Bloodborne Pathogen Preamble documents the regulatory discussions pertaining to how OSHA determined that anything infectious must be fluid or capable of releasing fluid when compressed. An extract of this preamble is provided in Appendix D. Page 2 of that document gives a good description of the compression and fluid considerations with very insightful background into the classifications and risk considerations.

An extract from the past trial EPA Medical Waste Tracking Act, where the EPA set the definitions for RMW, is provided in Appendix E because the OSHA preamble in Appendix D refers to it. Page 12341 (second page of Appendix E) uses the term "saturated and/or dripping" for the blood and bandages classification (Class 3). This is the historical origin for the terminology "dripping or saturated".

Observed Treatment Process. Medical personnel do not submerge the wooden part of the stick directly into body fluids; only the tip is submerged into a wound. Any residual fluids that may drip onto the stick near the tip were in contact with the silver nitrate and potassium nitrate chemicals during treatment. The residual fluid dries in a matter of minutes due to the heat and chemical reaction of the silver/potassium nitrate solution, which provides antiseptic treatment during the chemical reaction. A black, charred stain is left by the chemical reaction and should not be mistaken for residual fluid stains. Any residual fluid stains will look brown, not black. Appendix B provides a picture of the used stick—one with a residual stain and one without for comparison.

Laboratory Testing. Upon request, the APHC (Prov) Waste Management Program attempted to submit used sticks to two MEDCOM medical microbiology labs to test for biohazardous growth as an investigational study. In both requests, microbiology personnel rejected the sticks from testing because they were too dry to support microbiological growth for biohazard testing purposes. Microbiologists cannot test for a pathogen without viable body fluids to swab for the test. Swabbing a dry stain on the stick will not support biohazardous growth on the culture medium. The lack of fluids for laboratory testing further indicates the inability for infectious growth on the sticks.

State Environmental RMW Regulatory Reviews. States classify RMW as a special classification of solid waste. The EPA does not regulate RMW treatment and disposal more stringently than other types of solid waste. States have the option to enact RMW regulations but are not required to meet any minimum Federal standards for RMW treatment and disposal. Consequently, a wide variety of RMW definitions and terms are in effect throughout the fifty states. In fact, the environmental regulations in many states do not address all facets of RMW generation from characterization, segregation, collection, packaging, transport, treatment and disposal. Instead, multiple state government regulatory agencies including environment, public health, labor, and transportation regulate RMW generated in healthcare settings. However, Federal regulations do apply to worker protection when handling and transporting RMW. The OSHA Bloodborne Pathogen Standard is applicable in all fifty states, and is, therefore, the basis for determinations of what is an RMW generated in a healthcare setting. The APHC (Prov) conducted a comprehensive review of state RMW regulations and did not identify any state requirements that would classify the used silver nitrate sticks as RMW.

Regulated Medical Waste Assessment Conclusion. Dried blood stains on the sticks are not RMW and require no RMW management because: (1) the stains are not fluid or caked in a way that meets the OSHA Blood Borne Pathogen, state, or MEDCOM RMW regulations for an RMW; and (2) the dry physical state of the sticks will not support biohazardous growth.

WASTE MANAGEMENT

This waste must be processed for HW treatment and disposal through the Defense Logistics Agency (DLA) Disposition Services as a D001/D011 waste. The DLA Disposition Services will accept waste silver nitrate sticks with a signed certification statement declaring the waste is not an OSHA biohazard or a state infectious/medical waste. An example certification statement is provided in Appendix F. Medical personnel should place the sticks into a sealable bag or container to prevent exposure to any liquids that could result in additional release of the remaining silver/potassium nitrate solid on the stick tips. Collection in bags or tubes will prevent direct handling by DLA waste managers and contractors and should eliminate any concerns with the stains.

TIP No. 37-055-0516

POINT OF CONTACT

For additional information, contact the APHC (Prov) Waste Management Program at 410-436-3651.

Dated: May 2016

Prepared By: APHC (Prov) Waste Management Program

APPENDIX A

References

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EPA. *Health and Environmental Agencies of U.S. States and Territories*.
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EPA. *Links to Hazardous Waste Programs and U.S. State Environmental Agencies*.
<https://www.epa.gov/hwgenerators/links-hazardous-waste-programs-and-us-state-environmental-agencies>

EPA. Medical Waste. <https://www.epa.gov/rcra/medical-waste>

MEDCOM Regulation, 40-35 Regulated Medical Waste, July 2014.

OSHA. *Bloodborne Pathogen Standard, Frequently Asked Questions, Regulated Waste*. (See Appendix C.)
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OSHA. *Bloodborne Pathogen Standard, Preamble, Section 9, Summary and Explanation of the Standard*. (See Appendix D.)
https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=PREAMBLES&p_id=811

Title 29 CFR Part 1910, Section 1910.1030(b), Bloodborne Pathogen Standard.

Title 40 CFR Part 261, Identification and Listing of Hazardous Waste.

State Medical Waste Regulations

Alabama

Department of Environmental Management, Land Division,
Medical Waste Program, Division 17

Regulation: ADEM Administrative Code Rule 335-17

<http://www.adem.state.al.us/alEnviroRegLaws/default.cnt>

Alaska

Department of Environmental Conservation, Solid Waste Management

Regulation: Title 18 AAC 60.030

[http://www.legis.state.ak.us/basis/folioproxy.asp?url=http://www.jnu01.legis.state.ak.us/cgi-bin/folioisa.dll/aac/query=\[JUMP:'18+aac+60!2E030'\]/doc/{@1}/hits_only?firsthit](http://www.legis.state.ak.us/basis/folioproxy.asp?url=http://www.jnu01.legis.state.ak.us/cgi-bin/folioisa.dll/aac/query=[JUMP:'18+aac+60!2E030']/doc/{@1}/hits_only?firsthit)

Arizona

Department of Environmental Quality, Solid Waste Management

Regulation: Title 18 Article 14, Biohazardous Medical Waste and Discarded Drugs,
R18-13-1401

<http://www.azdeq.gov/environ/waste/solid/rules.html>

Arkansas

Department of Health, Management of Medical Waste

Regulation: Rules and Regulations Pertaining to the Management of Medical Waste
from Generators and Health Care Related Facilities

<http://www.healthy.arkansas.gov/aboutADH/Pages/RulesRegulations.aspx>

California

Department of Health Services, Medical Waste Management Program

Regulation: California Health and Safety Code, Sections 117600-118360

<http://www.cdph.ca.gov/certlic/medicalwaste/Pages/default.aspx>

For specific local requirements go to

<http://www.cdph.ca.gov/certlic/medicalwaste/Pages/LEAs.aspx>

Colorado

Department of Public Health and Environment,

Hazardous Materials and Waste Management

Regulation: 6 CCR 1007-2; Part 1 Regulations Pertaining to Solid Waste Sites and
Facilities, Section 13 Infectious Waste Disposal

<https://www.colorado.gov/pacific/cdphe/solid-waste-regulations>

Medical and pharmaceutical waste guidance for Health Care Facilities:

<https://www.colorado.gov/pacific/cdphe/medical-and-pharmaceutical-waste-guidance>

Connecticut

Department of Environmental Protection, Solid Waste Management
Regulation: Chapter 446d, Section 22a-209b and 209c

<http://www.cga.ct.gov/2011/pub/chap446d.htm>

http://www.ct.gov/dep/cwp/view.asp?a=2718&q=325340&depNav_GID=1646

Delaware

Department of Natural Resources, Division of Air and Waste Management
Regulation: Section 11, Special Wastes Management

www.dnrec.state.de.us/dnrec2000/Divisions/AWM/hw/sw/guides/infwaste.htm

Florida

Department of Environmental Protection, Department of Health
Regulation: FAC 64E-16, Biomedical Waste

<http://www.doh.state.fl.us/environment/community/biomedical/index.html>

Georgia

Department of Natural Resources, Environmental Protection Division
Regulation: Chapter 391-3-4-.15, Solid Waste Management, Biomedical Waste

<http://rules.sos.state.ga.us/gac/391-3-4>

Hawaii

Department of Health

Regulation: Title 11, Chapter 104.1, Management and Disposal of Infectious Waste

<http://health.hawaii.gov/opppd/departement-of-health-administrative-rules-title-11/>

<http://health.hawaii.gov/opppd/files/2015/06/11-104.1.pdf>

Idaho

Department of Health and Welfare

Rule: IDAPA 16.03.14, Rules and Minimum Standards for Hospitals in Idaho,

<http://adminrules.idaho.gov/rules/current/16/0314.pdf>

Illinois

Environmental Protection Agency

Rule: Title 35 IAC, Subtitle M: Biological Materials, Chapter I: Pollution Control Board,
Subchapter b: Potentially Infectious Materials, Parts 1420-1422

<http://www.ipcb.state.il.us/SLR/IPCBandIPEAEnvironmentalRegulations-Title35.aspx>

Indiana

State Department of Health

Regulation: IAC 16-41-16, Communicable Disease: Treatment of Infectious Waste

www.in.gov/legislative/ic/code/title16/ar41/ch16.html

Iowa

Department of Natural Resources

Regulation: IAC 567-100, Chapter 100, Environmental Protection Commission, Definitions, Forms and Rules of Practice

<https://www.legis.iowa.gov/law/administrativeRules/rules?agency=567&chapter=100&pubDate=03-24-2010>

Kansas

Medical Services Waste Division of Health and Environment,

Bureau of Waste Management

Regulation: KAR Article 29, Part 2, Standards for Management of Solid Waste, Chapter 28-29-27 Medical Services Waste

http://www.kdheks.gov/waste/regsstatutes/sw_laws.pdf

Kentucky

Division of Waste Management

Regulation: Kentucky Department for Environmental Protection, Division of Waste Management, Title 401, Chapter 49:005(1)(78)

http://waste.ky.gov/RLA/Pages/medical_waste.aspx

<http://waste.ky.gov/RLA/Documents/Table%201%20-%20Regulatory%20Overview%20of%20Medical%20Waste%20in%20Kentucky.pdf>

<http://www.lrc.state.ky.us/kar/title902.htm>

<http://labor.ky.gov/dows/oshp/doet/ETDocuments/ETPublications/BloodBorneBooklet.pdf>

Louisiana

Office of Public Health

Regulation: Title 51, Public Health Sanitary Code, Part XXVII Management of Refuse, Infectious Waste, Medical Waste and Potentially Infectious Medical Waste

http://www.lsbefd.state.la.us/wp-content/uploads/2014/08/51.XXVII_bio_waste.pdf

Maine

Department of Environmental Protection

Bureau of Remediation and Waste Management

Regulation: Title 06-096 Chapter 900, Biomedical Waste Management Rules

<http://www.maine.gov/sos/cec/rules/06/096/096c900.doc>

Maryland

Department of Health and Mental Hygiene, Department of Environment

Regulation: COMAR Title 10.06.06, Communicable Disease Prevention - Handling, Treatment and Disposal of Controlled Hazardous Substances,

COMAR Titles 26.13.11, 26.13.12 and 26.13.13

<http://www.dsd.state.md.us/COMAR/ComarHome.html>

Massachusetts

Department of Public Health, Community Sanitation Program
Regulation: 105 CMR 480.000, Minimum Requirements for the Management of Medical or Biological Waste (State Sanitary Code Chapter VIII)
<http://www.mass.gov/eohhs/docs/dph/regs/105cmr480.pdf>

Michigan

Department of Environmental Quality
Regulation: Part 138 Sections 333.13801-325.1549, Medical Waste Regulatory Act
http://www.michigan.gov/deq/0,1607,7-135-3312_4119---,00.html

Minnesota

Pollution Control Agency
Regulation: Minnesota Administrative Rule Parts 7035.9100-9150
<https://www.revisor.mn.gov/rules/?id=7035&view=chapter>

Mississippi

State Department of Health
Regulation: "Adopted Standards for the Regulation of Medical Waste" in Health Care Facilities Licensed by the State Department of Health"
<http://www.msdh.state.ms.us/msdhsite/index.cfm/30,116,83,pdf/licensureinfecreg%2Epdf>
Medical Waste Fact Sheet:
[http://www.deq.state.ms.us/mdeq.nsf/pdf/SW_MDEQMedicalWasteFactSheet/\\$File/MedWasteFactSheet.pdf?OpenElement](http://www.deq.state.ms.us/mdeq.nsf/pdf/SW_MDEQMedicalWasteFactSheet/$File/MedWasteFactSheet.pdf?OpenElement)

Missouri

Department of Natural Resources, Division of Environmental Quality
Regulation: 10 CSR 80-7, Infectious Waste Management
<http://www.sos.mo.gov/adrules/csr/current/10csr/10csr.asp>

Montana

Department of Environmental Quality
Regulation: Montana Code, Title 75-10-1001 Infectious Waste Management Act
http://leg.mt.gov/bills/mca_toc/75_10_10.htm

Nebraska

Department of Environmental Quality, Waste Management Division
Regulation: Title 132 Chapter 13.004, Rules and Regulations Pertaining to Solid Waste Management, Special Wastes:
<http://nlc1.nlc.state.ne.us/epubs/E6500/R015.0132-2006.pdf>

Nevada

Division of Environmental Protection, Bureau of Waste Management
Limited Regulation: Management of Special Waste
NAC 444.589, NAC 444, and NAC 444.662:

ndep.nv.gov/bwm/special.htm

<http://www.leg.state.nv.us/NAC/NAC-444.html>

New Hampshire

Department of Environmental Services, Solid Waste Management Bureau
Regulation: Chapter Env-Sw 904, Infectious Wastes

<http://des.nh.gov/organization/commissioner/legal/rules/index.htm#waste>

New Jersey

Department of Environmental Protection, Division of Solid and Hazardous Waste
Regulation: NJAC 7:26-3A, Regulated Medical Wastes

<http://www.nj.gov/dep/dshw/resource/2009%20RULES/26%20CHAPTER%203A.pdf>

New Mexico

Environment Department, Solid Waste Bureau

Regulation: 20 NMAC 9.1.105AL and 20NM AC 9.1.706 Paragraph F, Special Waste
Requirements, Infectious Waste

www.nmenv.state.nm.us/NMED_regs/swb/20nmac9_1.html

New York

Department of Health

Regulation: NYCRR Title 10 Part 70, Regulated Medical Waste

<http://w3.health.state.ny.us/dbspace/NYCRR10.nsf/56cf2e25d626f9f785256538006c3ed7/8525652c00680c3e8525652c004a59f3?OpenDocument>

New York State Guidance: <http://www.health.ny.gov/facilities/waste/>

North Carolina

Department of Environment and Natural Resources, Division of Waste Management
Regulation: 15A NCAC 13B .1200, Medical Waste Management

<http://deq.nc.gov/about/divisions/waste-management/waste-management-permit-guidance/solid-waste-section/medical-waste>

North Dakota

State Department of Health, Division of Waste Management,

Regulation: NDC Chapter 33-20-12, Regulated Infectious Waste

<http://www.legis.nd.gov/information/acdata/pdf/33-20-12.pdf>

<http://www.ndhealth.gov/wm/Publications/AGuideToUnderstandingNorthDakotasInfectiousWasteRegulations.pdf>

Ohio

State Environmental Protection Agency

Division of Solid and Infectious Waste Management

Regulation: OAC Chapter 3745-27, Solid and Infectious Waste Regulations

<http://codes.ohio.gov/oac/3745-27>

Oklahoma

Regulated Medical Waste Environmental and Natural Resources

Oklahoma Environmental Quality Code Title 252.515-1-2 and 252.515-23

<http://www.deq.state.ok.us/rules/515.pdf>

Oregon

Department of Environmental Quality, Land Quality

Regulation: Title 36 ORS 459.386-459.405

<http://www.deq.state.or.us/lq/sw/infectiouswaste/index.htm>

Pennsylvania

Department of Environmental Protection, Bureau of Waste Management

Regulation: Title 25 PAC 271.1 and Title 25 PAC 284

<http://www.pacode.com/secure/data/025/chapter284/chap284toc.html>

Puerto Rico

Environmental Quality Board

Regulation for the Management of Non-Hazardous Solid Waste, Chapter V, Rule 580

<http://www.temasactuales.com/assets/pdf/gratis/RegIDSNP.pdf>

Additional Guidance:

<http://www.oslpr.org/download/en/2008/A-0180-2008.pdf>

Rhode Island

Department of Environmental Management, Office of Waste Management

Regulation: DEM-DAH-MW-01-92, Rules and Regulations Governing the Generation

Transportation Storage, Treatment, Management and Disposal of Regulated Medical Waste

<http://www.dem.ri.gov/pubs/regs/regs/waste/medwaste10.pdf>

<http://www.dem.ri.gov/programs/benviron/waste/topmedwa.htm>

South Carolina

Department of Health and Environmental Control, Land and Waste Management

Regulation: R 61-105 Infectious Waste Management

<http://www.scdhec.gov/Agency/RegulationsAndUpdates/LawsAndRegulations/LWM/>

<http://www.scdhec.gov/Agency/docs/lwm-regs/R61-105.pdf>

South Dakota

Department of Environment and Natural Resources

Regulation: Article 74:27:07:01, Definition of Medical Waste

<http://legis.sd.gov/rules/DisplayRule.aspx?Rule=74:27>

Tennessee

Department of Environment and Conservation, Division of Solid Waste Management
Regulation: Chapter 0400-11-01, Solid Waste Processing and Disposal,
Rule 0400-11-01-.01 and Rule 0400-11-01-.04

<http://share.tn.gov/sos/rules/0400/0400-11/0400-11.htm>

Texas

Texas Commission on Environmental Quality, Municipal Solid Waste Division
Regulation: Title 30.330, Subchapter Y, Medical Waste Management

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http://www.tceq.state.tx.us/permitting/waste_permits/msw_permits/mw_disposal.html/#def

Utah

Department of Environmental Quality, Division of Solid and Hazardous Waste
Regulation: UAC R19-6-102 and UAC R315-316, Infectious Waste Requirements

<http://www.rules.utah.gov/publicat/code/r315/r315-316.htm>

Vermont

Department of Environmental Conservation, Waste Management Division
Guidance Document: "Procedure Addressing Regulated Medical Waste Definitions and
the Handling and Treatment of Regulated Medical Waste"

<http://www.anr.state.vt.us/dec/wastediv/solid/pubs/PROCEDFinal2.pdf>

Virginia

Department of Environmental Quality, Waste Management Board
Regulation: Title 9 VAC 20-120, Regulated Medical Waste Management Regulations

<http://law.lis.virginia.gov/admincode/title9/agency20/chapter120/>

<http://www.deq.virginia.gov/Programs/LandProtectionRevitalization/SolidHazardousWasteRegulatoryPrograms/MedicalWaste.aspx>

Washington

Department of Health

Regulation: RCW Title 79, Chapter 70.95K

<http://apps.leg.wa.gov/RCW/default.aspx?cite=70.95K>

West Virginia

Department of Health and Human Resources

Regulation: CSR Title 64-56, Infectious Medical Wastes

<http://www.wvdhhr.org/wvimw/index.asp>

<http://apps.sos.wv.gov/adlaw/csr/rule.aspx?rule=64-56>

<http://apps.sos.wv.gov/adlaw/csr/readfile.aspx?DocId=8726&Format=PDF>

Wisconsin

Department of Natural Resources, Waste Management Program

Regulation: WAC 287.07(7)(c)1c and WAC 526, Medical Waste Management

<http://docs.legis.wisconsin.gov/statutes/statutes/287/II/07/7/c/1/c>

http://docs.legis.wisconsin.gov/code/admin_code/nr/500/526.pdf

Wyoming

Department of Environmental Quality, Solid and Hazardous Waste Division

Additional Guidance: <http://deq.state.wy.us/eqc/orders/Air%20Closed%20Cases/13-2101%20AQD%20Rulemaking%20Chapters%203,4,5,6,8,11/Chapter%204%20-%20Final.pdf>

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APPENDIX B

USED SILVER NITRATE APPLICATOR STICK PICTURES

Figure B-1. Used stick tip with no residual fluid stain



Figure B-2. Used stick with stain next to stick with no stain



APPENDIX C

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)
BLOODBORNE PATHOGEN FREQUENTLY ASKED QUESTIONS EXTRACT
REGULATED WASTE

02/01/1993 - Most frequently asked questions concerning the bloodborne pathogens standard.

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Regulated Waste

Q36. What does OSHA mean by the term "regulated waste"?

A36. The Bloodborne Pathogens standard uses the term, "regulated waste," to refer to the following categories of waste which require special handling: (1) liquid or semi-liquid blood or OPIM; (2) items contaminated with blood or OPIM and which would release these substances in a liquid or semi-liquid state if compressed; (3) items that are caked with dried blood or OPIM and are capable of releasing these materials during handling; (4) contaminated sharps; and (5) pathological and microbiological wastes containing blood or OPIM.

https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=21010&p_text_version=FALSE#waste

APPENDIX D

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA)
BLOODBORNE PATHOGEN PREAMBLE EXTRACT

Section 9 - IX. Summary and Explanation of the Standard

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"Regulated Waste" was called "Infectious Waste" in the proposal. "Infectious Waste" was defined as blood and blood products, contaminated sharps, pathological wastes, and microbiological wastes. In this final standard, the analogous term "regulated waste" has been defined as: 1) liquid or semi-liquid blood or other potentially infectious materials; 2) contaminated items that would release with blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; 3) items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; 4) contaminated sharps; and 5) pathological and microbiological wastes containing blood or other potentially infectious materials. Based upon the collected information, OSHA has concluded that these items are generally recognized as presenting a hazard of disease transmission and as such, warrant special handling.

During the hearings, CDC/NIOSH testified:

The categories of items that we consider as potentially infectious and that should be handled in a special manner include microbiological waste, bulk blood or body fluid, contaminated blood, sharps or pathological waste, materials that contain those particular items would be defined by the CDC as infectious waste. (Ms. Polder - CDC/NIOSH, Tr. 9/14/89, p.54)

CDC explains their position further in their written comment, stating:

... As a related point of information, CDC considers it important to use the CDC definition of infectious waste, which has been adopted by OSHA in this proposed rule, in preference to the definition of medical waste adopted by EPA and used in the Medical Waste Tracking Act. The CDC definition is based on the epidemiology of disease transmission, whereas other definitions are much broader and include articles that should not require special handling. (CDC/NIOSH, Ex. 20-634)

With regard to EPA and their definition of wastes requiring special handling, some commenters expressed opinions similar to CDC and discouraged adoption of EPA's Medical Waste Tracking Act (MWTa) definition (e.g., APIC - Indiana, Ex. 20-139; McLeod Regional Medical Center, Ex. 20-527; Meadville Medical Center Ex. 20-624). However, other participants recommended that the MWTa definition be incorporated into the final standard (e.g. ADA, Ex. 20-665; Support Systems International, Ex. 20-1149). On a more general level, comments were also received which simply encouraged OSHA to assure that the final regulation's definition of "infectious waste" does not conflict with EPA's definition (e.g., AHA, Ex. 20-352; Tucson Medical Center, Ex. 20-141; Hospital of St. Raphael, Ex. 20-289).

In their comment on the proposal, EPA states:

The proposed OSHA definition appears to be fairly consistent with the wastestreams EPA regulates in 40 CFR Part 259, if the term "microbiological wastes" corresponds to Class 1 wastes in 40 CFR 259.30(a)(1) ("Cultures and stocks of infectious agents..."). EPA's rules also may cover a broader range of wastes, but generally do not refer to them as "infectious wastes" due to the wastes' widely varying infective capability. (EPA, Ex. 20-991)

Reviewing 40 CFR Part 259 reveals that microbiological wastes, as OSHA has defined them in this final regulation, would fall under Class 1 since the presence of blood or other potentially infectious materials is, under universal precautions, assumed to indicate the presence of a disease-causing bloodborne pathogen. EPA goes on to remark that their rules may cover a broader range of wastes. OSHA does not feel that this presents a conflict of definitions since the wastes regulated under this rule are a subset of those regulated by EPA. The Agency has concluded that the wastes covered under this standard warrant special handling and are in accordance with both CDC and EPA definitions. Therefore, these categories of waste have been retained in this regulation with modifications adopted in response to public comment.

Several participants commented on the ability of medical waste to transmit disease (e.g., Good Samaritan Hospital, Ex. 20-1230; Anaheim Medical Center, Ex. 20-45; Lewis-Gale Hospital, Ex. 20-871). In conjunction with this, a number of commenters raised the issue of the necessity of regulating the handling of certain components of the medical wastestream such as blood-stained bandages which could fall under the proposed definition but which they felt posed no threat of disease transmission (e.g., Palomar Pomerado Hospital, Ex. 20-1260; Rowan Memorial Hospital, Ex. 20-629; Community Hospital of Chula Vista, Ex. 20-761). Reviewing the record, it was noted that very little information is available on the potential for contracting disease as a result of contacting medical waste. The primary basis for comments that medical waste is no more infectious than household waste seems to be several German studies conducted in the early to mid-1980's comparing bacterial load of hospital wastes which are usually collected daily with that of household waste that was up to 7-days old (Exs. 286C; 286T; 286W). The Agency does not intend to debate the merits of these studies and has not conducted original research in this area. Hence, OSHA cannot offer a more definitive determination of the "infectiousness" of these materials. To eliminate the implication that OSHA has determined the "infectiousness" of certain medical wastes, the aforementioned waste categories have been grouped under the term "Regulated Waste" rather than "Infectious Waste."

Non-sharp waste, such as bandages, can be contaminated with widely varying amounts of blood or other potentially infectious materials, ranging from a single drop to complete saturation. The proposal contained no specific reference to how blood-contaminated non-sharp waste was to be differentiated and handled but simply stated that blood and blood products were to be treated as infectious waste. During the informal public hearings, the Agency solicited information from participants regarding what criteria were currently being utilized to determine which of these types of wastes were treated as "infectious" and which wastes were placed into the general waste stream. Responses to this inquiry were widely divergent, ranging from considering only blood-saturated items as infectious waste (Nassau-Suffolk Hospital Council, Inc., Tr. 11/14/89, pp.466-467) to "red-bagging" all items contaminated with blood or body fluids (Baptist Medical Center Montclair, Tr. 9/19/89, p.98; Laura Williams - SEIU, Tr. 10/17/89, pp.66-67). In addition, several interested parties requested that OSHA clarify what wastes were encompassed by the phrase "blood and blood products" (e.g., Greater New York Hospital Association, Tr. 11/14/89, p.316; APIC - Greater Los Angeles, Ex. 20-213). It became obvious to the Agency that no generally-accepted criteria was being applied by those involved to classify which blood-contaminated non-sharp waste required special handling. Therefore, an easy-to-use, acceptable minimal benchmark would have to be developed to assure consistent compliance and enforcement in this area. A number of commenters offered suggestions as to what this benchmark should be. The majority of commenters who considered this issue suggested that only bulk blood be considered infectious waste (e.g., AHA, Ex. 20-352; Middle Tennessee Medical Center Inc., Ex. 20-105; Arizona Hospital Association, Ex. 20-69). The difficulty with this approach is that there is little agreement on how much blood constitutes "bulk blood." Some commenters recommended actual volume amounts of blood ranging from greater than 10 ml to more than 100 ml of blood (e.g., Kalispell Regional Hospital, Ex. 20-1212; Virginia Mason Hospital, Ex. 20-569; Providence Memorial Hospital, Ex. 20-744). The Agency has concluded that such a determination would be difficult to judge since the visual characteristics of a specific quantity of blood would vary based on the type and size of substrate on which it appeared. For example, 10 ml of blood on a bed sheet would appear as a spot while the same amount on a cotton ball would likely cause saturation and dripping. Suggestions offered by other participants included bulk blood and items heavily saturated with blood or which drip and splash (e.g., Redlands Community Hospital, Ex. 20-692; Mills-Peninsula Hospitals, Ex. 20-701; St. Anthony Hospital Systems, Ex. 20-221); waste heavily contaminated with blood (Cleveland Clinic Foundation, Ex. 20-563); blood soaked items - not blood stained items (e.g., Nassau-Suffolk Hospital Council, Inc, Tr. 11/14/89, p. 46); only

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bulk amounts of liquid or semi-liquid blood (i.e. pourable or ability to flow), excluding dried blood (e.g., APIC - Indiana, Ex. 20-139; APIC - Greater Omaha, Ex.20-943); and blood that readily separates from the solid portion of waste under ambient temperature and pressure (Paradise Valley Hospital, Ex. 20-217). The record indicates that a large number of commenters feel that bulk blood should be classified as infectious waste. Moreover, "bulk" blood seems to be generally associated with the ability to pour or flow. During the hearings, Ms. Polder of the CDC stated:

... [I]n terms of blood, we really feel that the only type of blood that you need to be concerned about, in terms of transmission of disease, is bulk blood, or bulk fluids that may contain blood which means essentially liquids. ... In terms of items that are contaminated with blood that may be dry or may be wet, but are contained in a material such as gauze or a bandage, the risk of transmission of a pathogen to a susceptible host is extremely unlikely, and therefore, that type of waste can be handled like any other waste that is collected in the community, that may be contaminated in the same fashion. (Tr. 9/14/89, p.92)

Consequently, this physical characteristic (i.e., the ability to pour, flow, drip, etc.) has been adopted as one of the attributes of waste being regulated under this standard.

Comments such as those submitted by APIC - Greater Omaha Area and Paradise Valley Hospital make it apparent that in some circumstances solid waste is capable of generating bulk (i.e. liquid or semi-liquid) blood (Exs. 20-943; 20-217). While an item which is freely dripping blood or other potentially infectious materials obviously falls into this category, some items may adequately contain these materials when in a static state yet liberate them when compressed. During accumulation of waste in a container, the weight of items toward the top of the container naturally compress those items beneath. Wastes may also be purposefully compacted in order to increase the amount of waste which can be placed into a single container. This compression could generate potentially infectious liquids which would then accumulate at the bottom of the container. If the container's barrier capability is compromised, these materials would be released, presenting an exposure and/or contamination hazard. An EPA guidance document addressing EPA's Medical Waste Tracking Act states:

... Only those fibrous items that are completely saturated with blood (or would drip with blood if squeezed), or non-fibrous items that have enough blood present that they are dripping, are regulated medical waste. ... (Ex.224, Attachment A)

Both the EPA document and the statement by Ms. Polder of the CDC indicate that blood or other potentially infectious materials which are contained in non-sharp contaminated waste, such as bandages, do not become a concern until these liquids are liberated from the substrate. The ability of the substrate to contain these substances is the deciding factor as to their proper handling and disposal. OSHA has therefore concluded that items contaminated with blood or other potentially infectious materials which would release these substances in a liquid or semi-liquid state if compressed should be considered regulated waste.

Dried blood or other potentially infectious materials could also pose a problem if these dried materials are released from a contaminated item during handling. A study by Bond et. al. (Ex. 20-634) showed hepatitis B virus could remain viable in dried material for up to seven days. Furthermore, CDC recognizes the potential for disease transmission by dried blood. In their 1989 document, Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers, CDC recommends to law enforcement personnel:

Airborne particles of dried blood may be generated when a stain is scraped. It is recommended that protective masks and eyewear or face shields be worn by laboratory or evidence technicians when removing blood stain for laboratory analysis. (Ex. 15)

Based on this prolonged viability and potential for infection, items that are heavily contaminated or "caked" with dried blood or other potentially infectious materials have been included in those situations where such dried materials could flake or fall off of the item during handling.

In summary, the category "blood and blood products" contained in the proposal has been more specifically delineated in the final standard to read: 1) liquid or semi-liquid blood or other potentially infectious materials; 2) items contaminated with blood or other potentially infectious materials which would release these substances in a liquid or semi-liquid state if compressed; and 3) items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling. This expansion and clarification provides easily-recognized criteria for determining OSHA's intent as to those wastes it considers, at a minimum, to require special handling.

Very little comment was received about the remaining three categories of (infectious) regulated waste. Marion Memorial Hospital appeared to be referring to sharps that have not been contaminated by bloodborne pathogens when they stated that many sharps are utilized in hospitals that are never exposed to a patient (Ex. 20-1269). In consideration of those circumstances in which contamination of a sharp by bloodborne pathogens is known not to exist, the term "sharps" has been revised to "contaminated sharps" in the final standard to clarify that, for the purposes of this standard, sharps which are contaminated with blood or other potentially infectious materials are the items with which OSHA is concerned. However, it should be noted that other local, State, and Federal agencies (e.g., EPA) may have more expansive regulations regarding sharps and their disposal based upon factors such as transmission of diseases other than bloodborne diseases, aesthetic concerns, or the physical puncture hazard of sharps in general.

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APPENDIX E

MEDICAL WASTE TRACKING ACT FEDERAL REGISTER EXTRACT

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to participate. Congress did not establish a "no less stringent" standard for these States. EPA will identify those States that elect to opt out in a later Federal Register notice.

3. Other States

States not mentioned above may elect to participate in the demonstration program. The Governor of a State electing to participate must petition EPA by April 24, 1989 to be included on the list of Covered States. The definition of "State" in RCRA section 1004(31) includes the several States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands. EPA interprets the term "Governor" to include the Governor in any of the several States, or the equivalent head of the executive branch of the government for those other governmental entities. The Act specifies that EPA must determine whether to include a petitioning State in the program within 30 days of receipt of the petition (RCRA section 11001(c)). American Samoa has already petitioned to be included in the program, and EPA will make a determination regarding American Samoa and any other petition-in States after the 30 day period.

The Agency is planning to publish the final list of Covered States in the Federal Register shortly after the April 24, 1989, opt-out/petition-in deadline.

D. Subpart D—Regulated Medical Waste

Section 11002 of RCRA requires EPA to develop and promulgate a list of medical wastes to be tracked under the demonstration program. The statute provides the basic components of the list by identifying five waste types that must be included: (1) Cultures and stocks of infectious agents and associated biologicals; (2) pathological

waste; (3) human blood and blood products; (4) used sharps (e.g., syringes, needles, and surgical blades); and (5) contaminated animal carcasses. The statute also identifies five additional waste types that EPA is authorized to exclude from the demonstration program if the Agency determines that mismanagement of such wastes would not pose a substantial threat to human health or the environment; (6) surgery or autopsy waste; (7) laboratory wastes; (8) dialysis wastes; (9) discarded medical equipment; and (10) isolation wastes. The Act also gives EPA authority to add other medical wastes to the list if the Agency determines that such wastes may pose a substantial threat to human health or the environment.

The Act's designation of two different "universes" of medical waste originates, in part, from EPA's *Guide for Infectious Waste Management* (1986). In that document, the Agency identified two universes of medical waste: "infectious" medical waste and "miscellaneous contaminated wastes." The first universe, "infectious" medical wastes, included those wastes listed in the Act as waste types 1, 2, 3, 4, 5, and 10. The Agency, at the time, believed that all of these wastes should be specially managed. The second universe included those wastes listed in the Act as waste types 6, 7, 8, and 9. EPA recognized that, depending on the specific characteristics of the "miscellaneous contaminated wastes," they could be handled appropriately as "infectious" medical wastes or noninfectious medical wastes based on the determination of a responsible infection control practitioner.

Clearly, one of the most controversial aspects of EPA's guidance document has been its inclusion of isolation wastes (waste type 10 in the Act) in the first universe of "infectious" medical wastes.

The health care community, medical professionals, and public health officials have strongly criticized this aspect of the guidance document stating that, except under special circumstances, isolation wastes are unlikely to pose a significant hazard to human health or the environment. Thus, EPA believes that Congress, in formulating the statutory list of medical wastes subject to the demonstration program, relied on the basic format of the original waste listing as set forth in the 1986 guidance document (i.e., separating the universe of medical waste into "infectious" and "miscellaneous contaminated waste" categories). However, EPA also believes that Congress concurred with prevailing scientific opinion concerning the relative threat posed by isolation patient waste (listed in the EPA guidance document as an infectious waste category) and designated this as a category that the Administrator may exclude from the demonstration program based on the authority of section 11002(b).

In today's rule, medical wastes to be tracked under the demonstration program are referred to as "regulated medical waste." Regulated medical waste is a subset of medical waste which, in turn, is a subset of "solid waste" as defined in RCRA section 1004. This relationship is illustrated in Figure 1. The term "regulated medical waste" includes the list of medical wastes, as determined by EPA, and certain mixtures of these wastes with other types of wastes. This section of the Preamble discusses the criteria used to define or designate medical waste as "regulated medical waste," explains the content and rationale behind the regulatory listing of regulated medical waste, and describes the conditions under which waste classes may be exempted from regulation.

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MWTA was clearly intended to address this type of degradation.

Intravenous bags are being included in this category because they may continue to resemble blood bags even after certain treatment processes. Although intravenous bags may not have come into contact with any pathogenic microorganisms, the aesthetic degradation of the environment caused when they are mismanaged warrants their inclusion in the demonstration tracking program. EPA is using the authority under RCRA section 11002(a)(11) to list these items, and is including these items in this part of the regulation for convenience.

Class 3 also includes items that are saturated and/or dripping with human blood or that were saturated and/or dripping but have since dried. These wastes are aesthetically objectionable and, while they may present low potential for causing adverse health effects, in certain instances they pose a potential health threat if mishandled in the presence of other waste material such as sharps. This concern should only be present if the blood is in liquid form. Items with large quantities of dried blood are not likely to transmit disease. The blood is generally not present in a form (i.e., liquid) likely to pose a significant hazard to the persons handling the waste, but blood-caked items may still cause environmental (aesthetic) degradation, so these items are included in Class 3 as described above.

d. *Class 4—Used Sharps.* EPA's regulatory description of Class 4, used sharps, is based on section 11002 (a)(4), and reads as follows:

Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories, including hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, test tubes, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.

Sharps, with the exception of certain glassware, as explained below, are universally recognized as requiring stringent regulation under this program, given the unique bio and physical hazards as well as environmental degradation problems associated with used sharps (unused sharps are addressed in a separate class). The statutory waste type description has been modified slightly to clarify that sharps generated in care of both humans and animals are covered. It also includes the word "treatment" to cover

sharps generated from the preparation of human and animal remains for burial or cremation. Syringes are included under this class regardless of whether a needle is attached because EPA believes that this interpretation is consistent with the intent of Congress under the Medical Waste Tracking Act to minimize further improper disposal of aesthetically offensive medical wastes in the natural environment. Blood vials and culture dishes, which may also meet the descriptions of Waste Classes 3 and 1, respectively, were included in this class because the packaging requirements for sharps are more protective of waste handlers. Needles with attached tubing are included because of the physical and biohazard that may be present with the needle.

EPA has included in Class 4 certain wastes from RCRA section 11002(a)(7). These wastes are slides and cover slips that were in contact with infectious agents. In general, laboratory glassware that was not in contact with infectious agents does not pose the same kinds of aesthetic concerns as other sharps and is already adequately managed as general refuse. Therefore, only slides and cover slips that were in contact with infectious agents are listed in Class 4.

Finally, because the physical and aesthetic concerns are independent of the nature of medical service provided, EPA interprets Class 4 to cover sharps used in veterinary services as well as human patient care.

e. *Class 5—Animal waste.* EPA's description of Class 5 is based on section 11002(a)(5), and reads as follows:

Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals, or testing of pharmaceuticals.

Two modifications were made to the statutory language to clarify the wastes included in this class. First, the phrase "known to have been" was added to emphasize that only wastes from animals known to have been exposed to infectious agents during research are regulated medical waste. Without this phrase, it would be difficult for generators to identify accurately those wastes that should be regulated, which would make both compliance with and enforcement of this regulation problematic. This definition does not include household pets, farm animals, or wastes from farm animals unless they were exposed to infectious agents during research, production of

biologicals, or testing of pharmaceuticals.

The second clarification includes veterinary hospitals as an example of a research facility. This was suggested by attendees at EPA's medical waste meetings, because such facilities may generate contaminated animal waste. Wastes generated by general veterinary practices (e.g., small animals) are not covered in Class 5. However, the reader should note that sharps from veterinary services are covered under Class 4.

As guidance in determining what organisms are "infectious agents", the reader may use those agents identified in Classes 2 through 4 of the CDC's *Classification of Etiologic Agents on the Basis of Hazard* (July, 1974, available in the docket). Because EPA's definition of "infectious agent" in § 259.10 is limited to those organisms that cause disease or adverse health impacts in humans, only animal wastes potentially posing a hazard to human health are covered in Class 5.

f. *Class 6—Isolation wastes.* EPA's regulatory description of this class is identical to section 11002(a)(10) in all but one respect, and reads as follows:

Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from humans who are isolated to protect others from highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.

Although the statute refers to "communicable diseases" generally, the Agency believes that only certain highly communicable diseases should be included in the demonstration program. Health care professionals recommend that the scope of this class be limited to only those specific diseases that are sufficiently communicable to pose a potential threat to public health (for example, diseases caused by those agents listed in Classification 4 by the CDC in *Classification of Etiologic Agents on the Basis of Hazard* (1974)).

The Agency considered regulating all wastes from isolation patients, but concluded that many of the waste items are already covered under other waste classes, and that regulating all wastes from isolation patients would needlessly subject large amounts of waste to handling and packaging according to the requirements of the tracking program even though the large majority of such waste would be neither infectious nor aesthetically objectionable. For example, health care facilities have the option of assessing which isolation wastes, in addition to those required by these regulations, should be managed as regulated medical waste. EPA requests

APPENDIX F

Example Certification Statement for DLA Disposition Services

Office Symbol

Date

MEMORANDUM FOR RECORD

SUBJECT: Silver Nitrate Applicator Stick Waste

I certify the waste silver nitrate sticks are neither an OSHA regulated biohazard waste nor a State infectious/regulated medical waste.

Name

Title